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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/685,134      | 10/14/2003  | James F. Zucherman   | KLYCD-05009US1      | 4485             |

7590 02/12/2007  
Sheldon R. Meyer  
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San Francisco, CA 94111-4156

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| EXAMINER |
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HOFFMAN, MARY C

|          |              |
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| ART UNIT | PAPER NUMBER |
|----------|--------------|

3733

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE  | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS                               | 02/12/2007 | PAPER         |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/685,134

Applicant(s)

ZUCHERMAN ET AL.

Examiner

Mary Hoffman

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11/08/2006, 11/08/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 and 33-50 is/are pending in the application.
- 4a) Of the above claim(s) 5,6 and 33-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-12 and 47-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 12/10/04, 10/3/05, 1/9/07.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/07/2006 has been entered.

### ***Election/Restrictions***

Applicant's election of Species A, claims 1-12 and 47-50, in the reply filed on 11/08/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

It is noted that comparison of the claims with Figure 7a-7c and the specification shows, however, that the species of Figure 7a-7c does not have blade protector as required in claims 5 and 6. Claims 5-6 are now withdrawn (in addition to previously withdrawn method claims 33-46) from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/08/2006.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 and 7-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim(s) fail to define the invention in the manner required by 35 U.S.C. 112, second paragraph because they contain indefinite language. The structure which goes to make up the device must be clearly and positively specified. The structure must be organized and correlated in such a manner as to present a complete operative device. In claim 1, the structure is unclear. The examiner is interpreting claim 1 to mean that "wherein said first and said second tines **both** having an inner side and an outer side" (lines 3-4), and "a first cutting blade extends from **each** of the inner sides" (line 5), and "a second cutting blade extends from **each** of the outer sides" (line 9).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7-11 and 47-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Bertagnoli (U.S. Patent 5,571,109), previously cited.

Bertagnoli discloses a tool (see marked-up figure below of Figs. 7a-7b) that can be used as a cutter. The cutter has a forked end having two a first tine and a second tine, wherein the first and said second tines having an inner side and an outer side, a first cutting blade extending from the inner side of each of the inner sides of the first and second tines and extending in a first direction from said first and said second tines; wherein the first cutting blade is adapted to cut a groove in a first vertebral body in the first direction, and a second cutting blade extending from an outer side of said first and said second tines and extending in a second direction from said first and said second tines; wherein the second cutting blade is adapted to cut a groove in a second vertebral body in the second direction; wherein the second direction being opposite from the first direction. The tool is hand-held, wherein the first and the second cutting blades are parallel to each other and over the entire length of the blade cutting surface, the first and second blades are parallel to the handle of the tool, such that with the handle blades will cut parallel grooves in the horizontal plane. The second cutting blades are placed further apart than the first cutting blades. The two tines have beveled leading edges. The cutting blades are coplanar with the inner side of each tine. The cutting blades are coplanar with the outer side of each tine. The first and second blades are positioned and adapted to bypass nerves. The tines have inboard and outboard beveled surfaces that converge and the first cutting blades have surfaces are continuous with the inboard beveled surfaces and the second cutting blades have surfaces that are continuous with the outboard beveled surfaces. The first cutting blades are upper

Art Unit: 3733

cutting blades and the second cutting blades are lower cutting blades. The second cutting blades are lower cutting blades positioned and adapted to bypass nerves.

A tool comprising a cutter for distracting the upper and lower vertebrae, a first pair of cutting blades protruding upwardly, and a second pair of cutting blades protruding downwardly. The cutting blades make parallel horizontal grooves, and the second blades are outboard of and spaced from the first blades. The blades extend in a plane lateral to the sagittal plane. The blades are parallel to the handle.

SEE MARKED UP FIGURE NEXT PAGE:

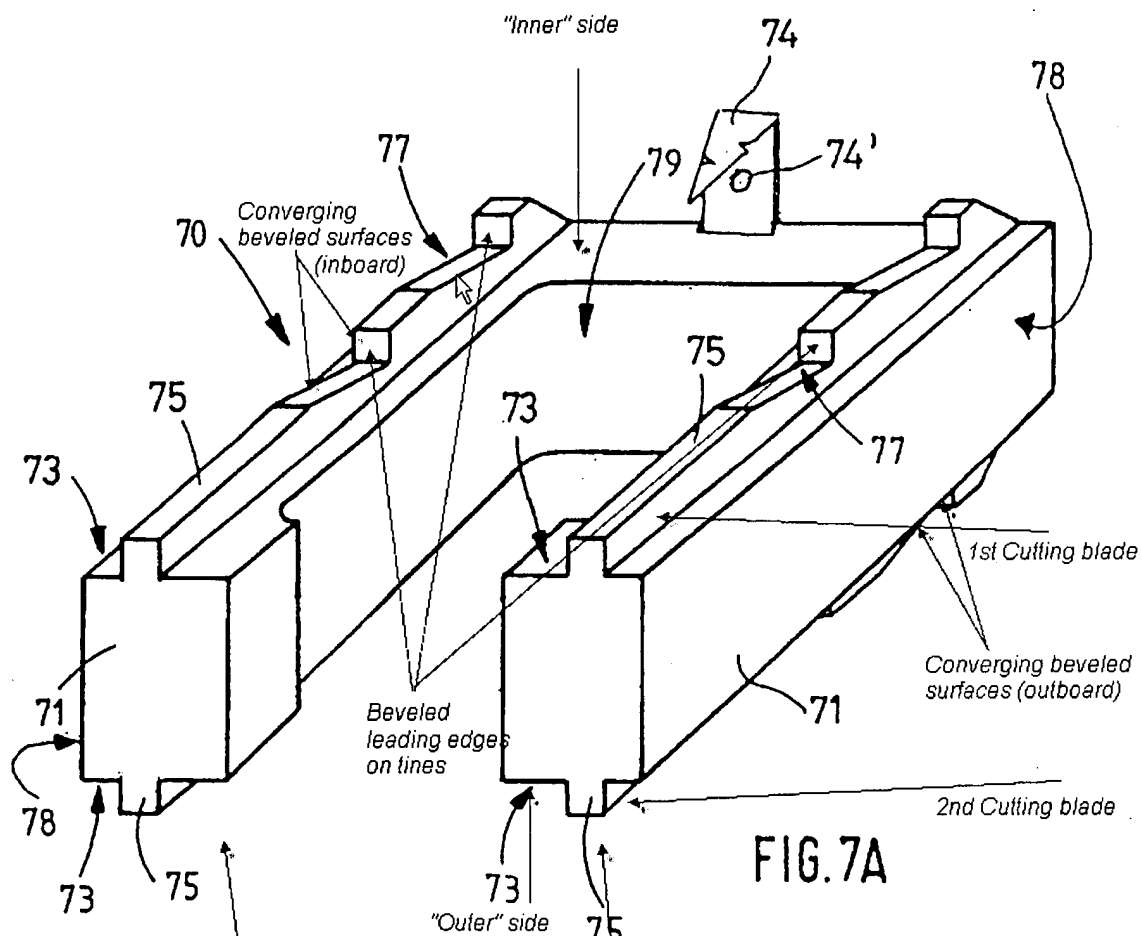
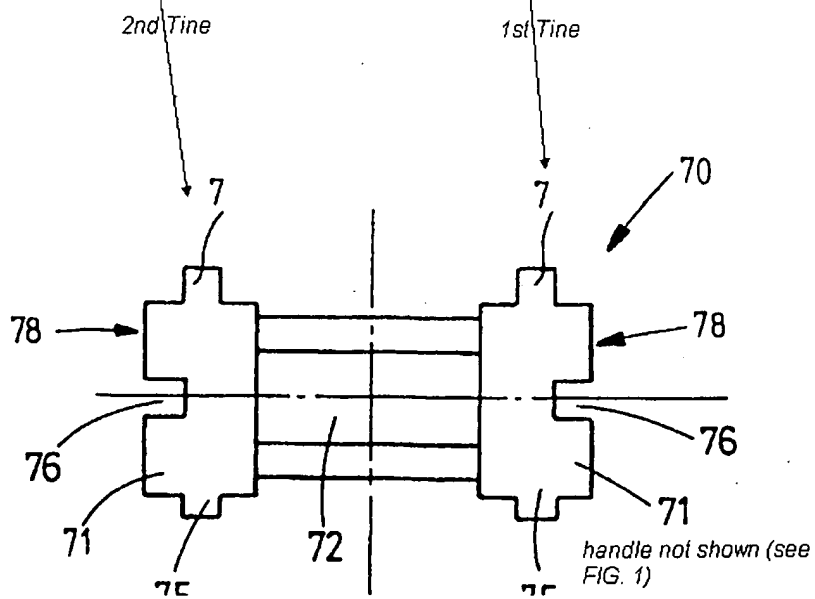


FIG. 7A



***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See attached PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

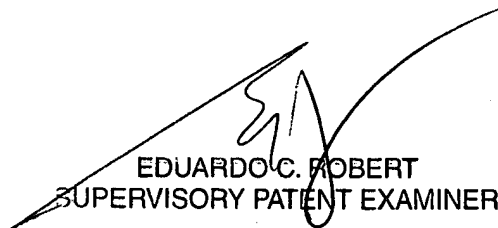
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 3733

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MCH



EDUARDO C. ROBERT  
SUPERVISORY PATENT EXAMINER